WRITTEN STATEMENT OF THE
AMERICAN COLLEGE OF GASTROENTEROLOGY
BEFORE THE HOUSE COMMERCE SUBCOMMITTEE ON HEALTH
AND THE ENVIRONMENT
ON
H.R. 15

I am Dr. Marvin M. Schuster, and I appear here today on behalf of the American College of Gastroenterology. I also currently serve as President of the American College of Gastroenterology and practice at The Johns Hopkins Bayview Medical Center in Baltimore Accompanying me today is Duane Smoot, M.D., Associate Professor. Gastroenterology Division. Howard University.

Colorectal Cancer Screening

Colorectal cancer is the second most frequent cancer killer in America, claiming the lives of 55,000 persons annually -- far more than either breast or prostate cancers. To achieve growth in survival, it is clear that progress must be made in the early detection of malignant lesions and their removal. Preventive care and early detection are paramount in improving survival prospects and providing cost-effective care. We applaud and wholeheartedly support the bipartisan effort which the "Medicare Preventive Benefits Improvement Act of 1997" (H.R. 15) represents for this and other important preventive health issues.

Many people believe colorectal cancer attacks men predominately. This is a myth Colorectal cancer strikes men and women in almost equal numbers. The high death rate from colorectal cancer proves especially tragic because it is a preventable type of cancer -- one that is curable when detected early. Most colorectal cancers develop from benign polyps and, when these polyps are removed, we can reduce the risk of colorectal cancer by 90 percent.

Unfortunately, the stark reality remains that too many of these cancers go undetected until they are past the curable stage.

These facts present a terrible contradiction in our system given that we have the tools through screening, early detection, and intervention, to eliminate up to 90 percent of these deaths, The American Cancer Society (ACS) has created preventive screening guideline recommendations for all Americans over the age of fifty. Ironically, Medicare patients are not covered for screening services.

In patients at higher risk for colorectal cancer by virtue of family history, chronic digestive disease condition including inflammatory bowel disease (Crohn's Disease or ulcerative colitis), the presence of any appropriate recognized markers for colorectal cancer or other predisposing factors, or prior cancerous or pre-cancerous lesions, surveillance colonoscopy usually proves medically appropriate. We folly concur with the provisions in H.R. 15 that define the category of high risk patients and provide this screening tool for patients recognized at high risk.

We specifically request that Congress enact the provisions in H.R. 15 -- namely, Medicare coverage for annual fecal occult blood testing, AND flexible sigmoidoscopy every four years as the two general screening mechanisms of choice for average risk, asymptomatic patients. **These two tests are inseparably linked -- together they will provide a valuable first line of defense against colorectal cancer, but neither will be effective unless provided in tandem with the other.** Additionally, for the asymptomatic patient who by virtue of family history, prior experience of cancer, its precursor neoplastic polyps. chronic history with a digestive disease condition, such as inflammatory bowel disease, or other predisposing factor, faces a significantly

higher risk for the disease, **it is essential that Medicare provide colonoscopy surveillance for these high risk individuals.**

Until Medicare begins to provide benefits that will encourage early detection and treatment, we stand little chance of markedly reducing the devastating impact and fatality rates of our nation's number two cancer killer.

Should the H.R. 15 screening regimen. which reflects the current core ACS recommendations for average risk patients. be expanded to include barium enema x-rav?

Barium x-ray yields a contrast image rather than the direct visualization made possible with flexible sigmoidoscopy and colonoscopy. Barium x-ray has a reduced specificity in identifying small to moderate-sized lesions. Unlike colonoscopy in which a single procedure can be both diagnostic and therapeutic to remove polyps and other lesions, barium enema x-ray is at best diagnostic without any ability to biopsy or remove a polyp. Every positive or inconclusive barium x-ray (15 to 20 percent of barium x-rays) requires another test, a colonoscopy.

Barium enema is less sensitive than colonoscopy for the detection of cancers and large polyps. In the National Polyp Study, a recent study involving seven university radiology departments, the sensitivity of double contrast barium enema for polyps, including polyps > 1 cm in size (those with the greatest risk of having cancer or turning into cancer) was less than 50 percent.

Some guidelines indicate a limited role for barium enema, recommending it for average risk individuals if used in conjunction with a flexible sigmoidoscopy. The screening regimen in

H.R. 15 tracks the ACS's current core recommendations for average risk patients, that is, the fecal occult blood test and flexible sigmoidoscopy. H.R. 15 provides inclusion of barium enema x-ray if and when sufficient evidence exists of its effectiveness and appropriateness to secure an affirmative recommendation from the Secretary of Health and Human Services (HHS).

Cost Considerations

Costs for implementing a Medicare colorectal cancer screening benefit such as that in H.R. 15 are modest, projected by the CBO to average $760 million over seven *years*. There is no independent CBO scoring on barium x-ray, but adding barium enema x-ray will cost taxpayers more. A health economist/consultant, who accurately projected the CBO score on the recommended regimen in H.R. 15, estimates that including barium x-ray would increase costs by almost 60 percent *(i.e.*, by about $460 million over seven years).

If, as is generally recognized from the scientific standpoint, colonoscopy proves the best available test for high risk patients because it alone directly visualizes the entire colon and offers the capability to convert contemporaneously to biopsy and/or remove many lesions/polyps, cost is not a reason to fail to establish colonoscopy as the standard of care for high risk patients, and we support the high risk patient provisions in H.R. 15.

Why Should Congress Decide on a Screening Regimen Rather Than Simply Defer to HCFA?

Nearly 55,000 Americans die each year -- deaths which could generally be avoided if Americans acted affirmatively in availing themselves of colorectal cancer screening. We need a

self-effectuating benefit -- Medicare beneficiaries need the screening benefit that H.R. 15 would provide, and they need it today. No one contests the role of the fecal occult blood test, the flexible sigmoidoscopy for average risk patients, or the colonoscopy for high risk patients. Congress needs to enact the colorectal cancer preventive benefit now. H.R. 15 provides that barium x-ray may be added, if and when HHS makes an affirmative finding of its effectiveness. Congress needs to enact the best, least expensive package now -- the one embodied in H.R. 15.

Addressing The Uniaue Needs of African-Americans in the Colorectal Cancer Screening Process

Some of you are aware that concerns have been raised about potential unique screening needs of African Americans, and whether the screening regimens referenced in H.R. 15 would recognize those needs. In addressing this issue, we have included for the record a copy of a letter to Representatives Charles Range1 and Edolphus Towns from Dr. LaSalle Leffall, recently retired as Dean and Chief of Surgery at Howard University Medical School, and a Past President of the American Cancer Society. What follows are some of the key points from that communication.

Recent evidence shows a somewhat increased tendency of colorectal cancers appearing in the proximal, i.e., more remote portions of the colon (higher in the digestive tract). This tendency applies to the general population, but data indicates that it may be more pronounced in African Americans. Articles have been published regarding this issue; however, research has not advanced to the point of it being established as a scientific fact. Established findings include:
(1) colon cancers are generally detected in African Americans at a more advanced stage;
(2) mortality from colorectal cancer is higher in African Americans than in the genera1

population; and (3) the quality of insurance coverage and access to medical care are issues contributing to African Americans' lack of regular screening. These three factors are likely interrelated.

The best means currently available for detecting and preventing colorectal cancer is colonoscopy. This remains the only procedure that also offers the physician the potential to intervene immediately at the time of diagnosis to simultaneously remove smaller cancerous or pre-cancerous lesions. Costs and other related considerations have caused us to refrain thus far from recommending this procedure for the average risk population, but H.R. 15 correctly identifies this as the screening mechanism of choice for high-risk patients. If scientific evidence ultimately establishes a significantly higher propensity for African Americans to suffer from right-sided, proximal cancers, colonoscopy should be provided for the most definitive screening. H.R. 15 as currently drafted furnishes the solution because it provides a high risk category of patients. Such patients may undergo a colonoscopy every two years and this test permits direct visualization of the entire colon.

In short, the screening regimen described in H.R. 15 seems the right one. If subsequent studies confirm the indications that more right-sided lesions (in the proximal colon) occur in African Americans, colonoscopy should be offered as the procedure of choice to address such increased risk factors. This can he accomplished by modifying the high risk definition to include any subset of the population with proven higher risk and a need for expanded testing. Colonoscopy enjoys the advantages of greater specificity and the opportunity for simultaneous excision of lesions. No modifications to the current provisions of H.R. 15 are required to address the needs of African Americans with regard to colorectal cancer screening.

Delay Implementing a Resource-Based Practice Expense Component in the Medicare Fee Schedule (MFS)

I would like to comment on one other issue under the jurisdiction of this Committee. Legislation created in 1994 required HCFA to develop a methodology for implementing a resource-based system for practice expense relative value units for physician services, and to report to the Congress by June 30, 1996. **To date, neither HCFA nor its** subcontractors has **compiled reliable data on actual medical practice cost factors** needed **for a resource-based approach to practice expenses.** HCFA awarded a contract to a firm that proposed to develop a database by surveying several thousand medical practices, convening panels of clinical practice experts. and compiling input price data. HCFA **and the outside contractor projeeted that the database would be completed by spring 1996. This deadline was not met.** Actual practice expenses still remain undocumented. Delays and problems in gathering data and complex data collection surveys impeded progress on this project. In 1996, HCFA canceled its contract with the outside contractor and assumed responsibility for completing the data collection and analysis -- tasks not yet completed.

Despite the lack of reliable data, HCFA still plans to issue a proposed rule by May 1, 1997, and a final rule before the end of the year. In early projections, HCFA says it expects that its recomputation of practice expense would reduce its total payments to most procedural and surgical specialties by up to 40 percent in 1998. Reductions in gastroenterology fees are projected to range between 20 and 24 percent. We urge Congress to amend the Social Security Act to delay implementation of resource-based practice expense relative values for at least two years, and direct HCFA to develop the practice cost component of the physician fee schedule

based on accurate and fairly collected data. HCFA must be told to document practice expenses accurately and must receive additional time to analyze the resulting data to test different ways of estimating practice costs for the different costs/services in the fee schedule.

Conclusion

Colorectal cancer kills 55,000 Americans each year -- more than either breast or prostate cancer. The terrible anomaly in our system is that we have the tools through screening, early detection and intervention to eliminate up to 90 percent of these deaths -- and cut treatment costs at the same time. Preventive care and early detection are of paramount importance in improving survival prospects and providing cost-effective care.

On behalf of the American College of Gastroenterology, I would like to reiterate our strong support for the enactment of H.R. 15 in its current form without modification. We also wish to thank the Committee for its bipartisan effort to add a colorectal cancer screening benefit to Medicare -- by virtue of age, our senior citizens represent a population group at greater risk for this cancer.